

REMARKS

I. PRELIMINARY REMARKS

Claims 1, 15, 24 and 39 have been amended. Claims 5 and 17 have been canceled. Claims 49-62 have been added. Claims 1, 3, 4, 6-16, 18-28, 33, 36, 37, 39 and 41-62 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes with appreciation that claims 12-14, 26-28, 33, 36 and 37 have been allowed.

II. CLAIMS 1, 3-11 AND 15-25

A. The Rejections

Claims 1, 3, 5-8, 11, 15-20, 24, 25 and 44 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the U.S. Patent No. 5,047,028 to Qian ("the Qian '028 patent") and U.S. Patent No. 5,255,678 to Deslauriers ("the Deslauriers '678 patent").

Claim 4 has been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Qian '028 patent, the Deslauriers '678 patent and U.S. Patent No. 5,329,923 to Lundquist ("the Lundquist '923 patent").

Claims 9 and 10 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Qian '028 patent, the Deslauriers '678 patent and U.S. Patent No. 5,961,513 to Swanson ("the Swanson '513 patent").

Claims 21-23 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Qian '028 patent, the Deslauriers '678 patent, U.S. Patent No. 5,569,241 to Edwards ("the Edwards '241 patent") and U.S. Patent No. 5,403,311 to Abele ("the Abele '311 patent").

As claims 5 and 17 have been canceled, it is respectfully submitted that the rejection under 35 U.S.C. § 103 has been rendered moot. The rejections of claims 1, 3, 4, 6-11, 15, 16, 18-25 and 44 under 35 U.S.C. §§ 102 and 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. Discussion Concerning Claims 1, 3, 4, 6-11, 15, 16 and 18-25

Independent claims 1 and 15 call for respective combinations of elements including, *inter alia*, "a relatively short, relatively stiff shaft," "an electrical conductor ... extending through the shaft," "an inflatable, energy transmitting lesion formation element associated with the distal portion of the shaft that allows substantially no liquid perfusion therethrough" and "an electrode, which defines an electrode diameter that is substantially larger than the conductor diameter, located within the inflatable, energy transmitting lesion formation element and operably connected to the electrical conductor." The cited references fail to teach or suggest such a combination.

The Qian '028 patent discloses a device which includes a tube 10, a balloon 12 and a conductive wire 16. In contrast to the claimed combination, the Qian balloon 12 creates thrombosis in blood vessels, not lesions. Additionally, there is no electrode connected to the Qian conductive wire 16.

It is also noteworthy that the Office Action stated on pages 8 and 9 that "Qian provides an RF electrode that is inherently capable of acting [as a lesion formation element]. The difference between creating a lesion and creating thrombosis is a matter of energy delivery and time." To the extent that the statement intended to convey that the Qian device is inherently capable of ohmically heating tissue at the balloon surface to a level sufficient to form a lesion, the statement is respectfully traversed.

First, with respect to purportedly inherent subject matter, the Federal Circuit stated that "[t]o serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with the recourse to extrinsic evidence" and that "such evidence must make it clear that the missing descriptive matter

is ***necessarily present*** in the thing described in the reference." *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (emphasis added). "Inherency ... may not be established by probabilities or possibilities." *Id.* Here, the Office Action has failed to provide any evidence which shows that the Qian wire and balloon arrangement will necessarily be capable of ohmically heating tissue at the balloon surface.

Second, applicant respectfully submits that the wire and balloon arrangement disclosed in the Qian patent simply will not ohmically heat tissue at the balloon surface to a level sufficient to form a lesion, no matter how long power is applied. More specifically, the diameter of a typical conductor wire in EP applications (i.e. 0.1-0.2 mm) is simply too small to provide enough power at the balloon surface to form lesions. Local power density is proportional to $1/r^2$. Thus, power 1 mm from the center of a 0.2 mm wire is about 1% of the power delivered at the wire surface. The power level decreases to 0.01% of the power delivered at the wire surface at a distance of 1 cm from center of the 0.2 mm wire. This problem cannot be solved by increasing power to very high levels because, as voltage is increased, the saline near the water will boil, which increases resistance. Nor can this problem be solved by applying the low power to the tissue for long periods of time because blood flow in the microvasculature results in convective heat loss in the tissue that prevents the tissue from ever getting hot enough to coagulate.

The Deslauriers '678 patent is directed to a mapping balloon and, accordingly, cannot remedy the deficiencies in the Qian '028 patent.

As the Qian '028 patent and Deslauriers '678 patent fail to teach or suggest the respective combinations of elements recited in independent claims 1 and 15, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 1, 3, 6-8, 11, 15, 16, 18-20, 24 and 25 under 35 U.S.C. § 103 is improper and should be withdrawn.

The Lundquist '923 patent and Swanson '513 patent, which have been cited with respect to dependent claims 4, 9 and 10, fail to remedy the above-identified deficiencies in the Qian '028 patent and Deslauriers '678 patent. For example, the Lundquist '923 patent and Swanson '513 patent do not suggest using a balloon that is designed to create

thrombosis in blood vessels for lesion formation. Applicant respectfully submits, therefore, that claims 4, 9 and 10 are patentable for at least the same reasons as independent claim 1 and that the rejections thereof under 35 U.S.C. § 103 should also be withdrawn.

C. Additional Discussion Concerning Claim 24

In addition to the elements recited in independent claim 15, the combination defined by claim 24 calls for a fluid source that “**continuously infuses fluid to and receives ventilated fluid from** the inflatable, energy transmitting lesion formation element.” The cited references fail to teach or suggest such a combination.

For example, the Qian '028 patent merely states that fluid is used to “inflate” and “fill” the balloon 12. [Column 1, lines 44-47 and column 2, lines 10-14.] There is no indication that fluid is continuously infused to and ventilated from the balloon 12. Moreover, to extent that the small amount of fluid that leaks from the balloon 12 could be considered “ventilated,” that fluid flows into the patient and is not received by the fluid source. Similarly, to the extent that the mapping electrode teachings of the Deslauriers '678 patent are even applicable to the thrombosis inducing device disclosed in the Qian '028 patent, the Deslauriers balloon is inflated with a syringe 26 and there is no indication that fluid is being continuously ventilated as it is supplied by the syringe.

As the Qian '028 patent and Deslauriers '678 patent fail to teach or suggest the combination of elements recited in claim 24, whether viewed alone or in combination, applicant respectfully submits that the rejection of claim 24 under 35 U.S.C. § 103 should be withdrawn for reasons in addition to those discussed above with respect to independent claim 15.

III. CLAIMS 39 AND 41-48

A. The Rejections

Claims 39, 41-43 and 45 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,800,484 to Gough ("the Gough '484 patent"). Claims 46-48 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Gough '484 patent, the Edwards '241 patent and the Abele '311 patent.

Claims 39, 41-43 and 45 have been rejected under 35 U.S.C. § 102 as being anticipated by the Qian '028 patent. Claim 44 has been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Qian '028 patent and the Deslauriers '678 patent. Claims 46-48 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings the Qian '028 patent, the Edwards '241 patent and the Abele '311 patent.

The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

B. The Claimed Combinations

Independent claim 39 calls for a combination of elements comprising "a surgical probe including .. an inflatable, energy transmitting therapeutic element associated with the distal portion of the shaft, an infusion lumen ... and a ventilation lumen" and "a cooling fluid source ... adapted to ... continuously infuse cooling fluid to the inflatable, energy transmitting therapeutic element by way of the infusion lumen and ***draw cooling fluid from the inflatable, energy transmitting therapeutic element by way of the ventilation lumen.***" The cited references fail to teach or suggest such a combination.

C. Rejections Based on the Gough '484 Patent

The Gough '484 patent discloses various multiple antenna ablation devices that are configured to deliver conductive fluid to tissue. More specifically, the Gough '484 patent discloses the use of a fluid delivery member 23 "that is sufficiently porous to permit the passage of fluid" as well as an expandable member 29 that may be used in combination with the fluid delivery member to enlarge the fluid delivery member. [Column 6, lines 34-36; and column 6, line 58 to column 7, line 30.] The Gough '484 patent also discloses the use of a "source of conductive medium." [Column 7, lines 8-25.] Although the "source of conductive medium" supplies fluid, it does not draw fluid from the fluid delivery member 23.

As the Gough '484 patent fails to teach or suggest each and every element in the combination defined by independent claim 39, applicant respectfully submits that the rejection of claims 39, 41-43 and 45 under 35 U.S.C. § 102 should be withdrawn.

The Edwards '241 patent and Abele '311 patent, which have been cited with respect to dependent claims 46-48, fail to remedy the above-identified deficiencies in the Gough '484 patent. Applicant respectfully submits, therefore, that claims 46-48 are patentable for at least the same reasons as independent claim 39 and that the rejection thereof under 35 U.S.C. § 103 should also be withdrawn.

D. Rejections Based on the Qian '028 Patent

The Qian '028 patent, as noted above, merely states that fluid is used to "inflate" and "fill" the balloon 12 and there is no indication that fluid is continuously infused to the balloon 12 by way of an infusion lumen. Nor is there any indication that fluid is continuously drawn from the balloon 12 by way of a ventilation lumen.

As the Qian '028 patent fails to teach or suggest each and every element in the combination defined by independent claim 39, applicant respectfully submits that the rejection of claims 39, 41-43 and 45 under 35 U.S.C. § 102 should be withdrawn.

Turning to the rejection of claims 44 under 35 U.S.C. § 103, the Deslauriers '678 patent discloses a balloon that is inflated with a syringe 26. There is no indication that fluid is being continuously drawn from the balloon as it is supplied by the syringe 26. As such, the Deslauriers '678 patent cannot remedy the deficiencies in the Qian '028 patent. Applicant respectfully submits, therefore, that claim 44 is patentable for at least the same reasons as independent claim 39 and that the rejection of claim 44 under 35 U.S.C. § 103 should also be withdrawn.

The Edwards '241 and Abele '311 patents, which have been cited with respect to dependent claims 46-48, fail to remedy the above-identified deficiencies in the Qian '028 patent. Applicant respectfully submits, therefore, that claims 46-48 are patentable for at least the same reasons as independent claim 39 and that the rejection thereof under 35 U.S.C. § 103 should also be withdrawn.

IV. NEWLY PRESENTED CLAIMS 49-62

Claim 49 depends from claim 24 and, accordingly, is patentable for at least the same reasons as claim 24.

Independent claim 50 calls for a combination of elements comprising "a relatively short, relatively stiff shaft defining a distal portion and a proximal portion" and "means, associated with the distal portion of the shaft, for inflating and transmitting current to tissue at a level sufficient to cause the formation of lesions without substantial liquid perfusion." The cited references fail to teach or suggest such a combination and, accordingly, claims 50-53 are patentable thereover.¹

Independent claim 54 calls for a combination of elements comprising "a surgical probe including a relatively short shaft defining a distal portion and a proximal portion

¹ The MPEP states that "the application of a prior art reference to a means or step plus function limitation requires that the prior art element perform the **identical function** specified in the claim." MPEP § 2182, emphasis added. Along these lines, the Federal Circuit stated that "[t]he corresponding structure to a function set forth in a means-plus-function limitation **must actually perform the recited function, not merely enable the pertinent structure to operate as intended.**" *Asyst Technologies Inc. v. Empak Inc.*, 60 USPQ2d 1567, 1672-73 (Fed. Cir. 2001), emphasis added.

and an inflatable, energy transmitting therapeutic element associated with the distal portion of the shaft" and "a cooling fluid source operably connected to the inflatable, energy transmitting therapeutic element and adapted to maintain pressure within the inflatable therapeutic element at a predetermined level and to continuously infuse and ventilate cooling fluid to and from the inflatable, energy transmitting therapeutic element." The claim also specifies that "at least some of the continuous ventilation of the cooling fluid occurs in a manner other than perfusion through the inflatable therapeutic element." The cited references fail to teach or suggest such a combination and, accordingly, claims 54-62 are patentable thereover.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

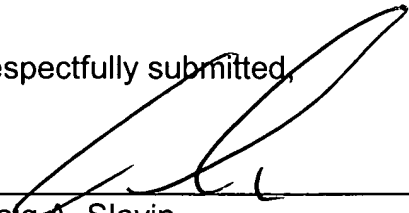
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

10/7/03
Date

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Respectfully submitted,



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